PHARMACY BOARD[657]

Notice of Intended Action

Proposing rule making related to bronchodilator canisters, bronchodilator canisters and spacers, and opioid antagonists and providing an opportunity for public comment

The Board of Pharmacy hereby proposes to amend Chapter 3, "Pharmacy Technicians," Chapter 6, "General Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 18, "Centralized Prescription Filling and Processing," Chapter 21, "Electronic Data and Automated Systems in Pharmacy Practice," and Chapter 39, "Expanded Practice Standards," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in 2022 Iowa Acts, House File 771.

State or Federal Law Implemented

This rule making implements, in whole or in part, 2022 Iowa Acts, House Files 771, 2573, and 2169.

Purpose and Summary

These proposed amendments implement changes to the Iowa Code made during the 2022 Legislative Session relating to licensed nurses engaging in the practice of nursing pursuant to a pharmacist's order and the issuance of a prescription in the name of a school district to obtain a bronchodilator canister, a bronchodilator canister and spacer, or an opioid antagonist.

Fiscal Impact

This rule making has minimal fiscal impact to the State of Iowa. The Board estimates that under this rule making, approximately 400 registered nurses will no longer be required to annually obtain a pharmacy technician registration for the administration of vaccines or utilization of a Board-approved statewide protocol under the order of a pharmacist. As such, annual registration fees may be reduced by approximately \$8,000.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on December 20, 2022. Comments should be directed to:

Sue Mears
Board of Pharmacy
400 S.W. 8th Street, Suite E
Des Moines, Iowa 50309
Email: sue.mears@iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

- ITEM 1. Amend subrule 3.3(1) as follows:
- **3.3(1)** Licensed health care provider. Except as provided in this rule, a licensed health care provider whose registration or license is in good standing with and not subject to current disciplinary sanctions or practice restrictions imposed by the licensee's professional licensing board and who assists in the technical functions of the practice of pharmacy shall be required to register as a certified pharmacy technician or pharmacy technician trainee pursuant to these rules. A registered nurse licensed pursuant to Iowa Code chapter 152 or 152E who is engaged in the administration of immunizations and vaccinations and the utilization of statewide protocols pursuant to a pharmacist's order is exempt from registration.

ITEM 2. Amend paragraph **6.10(1)"c"** as follows:

- c. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner, except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors, 657—subrule 8.19(8) for opioid antagonists, or 657—subrule 8.19(9) for expedited partner therapy, or 657—subrule 8.19(10) for bronchodilator canisters or bronchodilator canisters and spacers.
 - ITEM 3. Amend rule 657—8.19(124,126,155A) as follows:
- **657—8.19(124,126,<u>135,</u>155A,<u>280)</u> Manner of issuance of a prescription drug or medication order. A prescription drug order or medication order that is issued prior to January 1, 2020, or that is exempt from the electronic prescription mandate pursuant to rule 657—21.8(124,155A)** may be transmitted from a prescriber or a prescriber's agent to a pharmacy in written form, orally including telephone voice communication, by facsimile transmission as provided in rule 657—21.7(124,155A), or by electronic transmission in accordance with applicable federal and state laws, rules, and regulations. Any prescription drug order or medication order provided to a patient in written or printed form shall include the original, handwritten signature of the prescriber except as provided in rule 657—21.6(124,155A).
- **8.19(1)** Requirements for a prescription. A valid prescription drug order shall be based on a valid patient-prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors, and in subrule 8.19(8) for opioid antagonists, or subrule 8.19(10) for bronchodilator canisters or bronchodilator canisters and spacers.
- a. Written, electronic, or facsimile prescription. In addition to the electronic prescription application and pharmacy prescription application requirements of this rule, a written, electronic, or facsimile prescription shall include:
 - (1) No change.
- (2) The name and address of the patient except as provided in subrule 8.19(7) for epinephrine auto-injectors, subrule 8.19(8) for opioid antagonists, or subrule 8.19(9) for expedited partner therapy, or subrule 8.19(10) for bronchodilator canisters or bronchodilator canisters and spacers.

(3) to (5) No change.

b. to d. No change.

8.19(2) to 8.19(7) No change.

- **8.19(8)** Opioid antagonist prescription issued to law enforcement, fire department, of service program, or school district. A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more opioid antagonists in the name of a law enforcement agency, fire department, or service program pursuant to Iowa Code section 147A.18 and rule 657—39.7(135,147A), or in the name of a school district pursuant to Iowa Code section 135.190 and rule 657—39.7(135,147A). The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the law enforcement agency, fire department, or service program, or school district in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.
- a. The pharmacy's patient profile and record of dispensing of an opioid antagonist pursuant to this subrule shall be maintained in the name of the law enforcement agency, fire department, or service program, or school district to which the prescription was issued and the drug was dispensed.
- b. The label affixed to an opioid antagonist dispensed pursuant to this subrule shall identify the name of the law enforcement agency, fire department, or service program, or school district to which the prescription is dispensed and shall be affixed such that the expiration date of the drug is not rendered illegible.

8.19(9) No change.

- **8.19(10)** Bronchodilator canister or bronchodilator canister and spacer prescription issued to a school district or accredited nonpublic school. A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more bronchodilator canisters or bronchodilator canisters and spacers in the name of a school district or accredited nonpublic school pursuant to Iowa Code section 280.16A. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the school district or accredited nonpublic school in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.
- <u>a.</u> The pharmacy's patient profile and record of dispensing of a bronchodilator canister or bronchodilator canister and spacer pursuant to this subrule shall be maintained in the name of the school district or accredited nonpublic school to which the prescription was issued and the drug was dispensed.
- b. The label affixed to a bronchodilator canister or bronchodilator canister and spacer dispensed pursuant to this subrule shall identify the name of the school district or accredited nonpublic school to which the prescription is dispensed and shall be affixed such that the expiration date of the drug is not rendered illegible.

ITEM 4. Amend paragraph 18.3(4)"d" as follows:

d. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner, except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors, 657—subrule 8.19(8) for opioid antagonists, or 657—subrule 8.19(9) for expedited partner therapy, or 657—subrule 8.19(10) for bronchodilator canisters or bronchodilator canisters and spacers.

ITEM 5. Amend paragraph 21.8(1)"h" as follows:

h. A prescription issued for an opioid antagonist pursuant to Iowa Code section 135.190, or a prescription issued for epinephrine pursuant to Iowa Code section 135.185, or a prescription issued for a bronchodilator canister or bronchodilator canister and spacer pursuant to Iowa Code section 280.16A.

ITEM 6. Amend subrule 39.7(1), definition of "Person in a position to assist," as follows:

"Person in a position to assist" means a family member, friend, caregiver, health care provider, employee of a substance abuse treatment facility, school employee, or other person who may be in a position to render aid to a person at risk of experiencing an opioid-related overdose.